REMARKS

In the Office Action dated June 7, 2005, claims 18-22 were examined with the result that all claims were rejected. In response, Applicant has rewritten claim 18 and added new claims 30-34. In view of the above amendments and following remarks, reconsideration of this application is requested.

In the Office Action, claims 18-22 were rejected under 35 USC §103(a) as being unpatentable over DeLuca et al U.S. 5,843,928. The Examiner indicated that the rejection was directed only to the method of treating colon cancer, breast cancer and prostate cancer. The rejection appears not to have been made in connection with the treatment of leukemia. Accordingly, Applicant has revised claim 18 via the present Amendment to be limited to the treatment of leukemia, and has added new claims 30-34 directed toward a method of treating colon cancer, breast cancer or prostate cancer. Accordingly, Applicant believes claim 18 and claims 19-22 which depend from claim 18 should all now be allowable.

Since the above rejection was directed only toward treated colon cancer, breast cancer and prostate cancer, the following comments will be directed toward new claims 30-34 as these claims are limited to the treatment of such cancers with the claimed vitamin D compound (hereinafter 2MD). The Examiner's rejection appears to be based upon the Examiner's belief that the previous showing in the DeLuca Declaration is not commensurate with the scope of the original subject matter claimed. In other words, the Examiner indicated that the cell differentiation data presented in the DeLuca Declaration related to the inhibiting effect of 2MD on HL-60 cell differentiation which is a leukemia cell line and accordingly could not be correlated with other neoplastic disorders such as breast cancer, prostate cancer or colon cancer. Thus, the Examiner limited his rejection to treating those three cancers, but not leukemia. That, of course, is the basis for Applicant amending the claims to split leukemia from colon cancer, breast cancer and prostate cancer by limiting claim 18 to leukemia and presenting the treatment of colon cancer, breast cancer and prostate cancer in new claims 30-34.

Although the differentiation data presented is directed toward the effect of 2MD on HL-60 leukemia cells, Applicant believes these data can in fact correlate with treating colon cancer, breast cancer and prostate cancer. In support of Applicant's position, Applicant submits the following documents:

1. Van Leeuwen et al, "Vitamin D: Cancer and Differentiation", Vitamin D, Second Edition, Elsevier Academic Press, pp. 1571-1597 (2005).

2. DeLuca et al U.S. Patent 6,939,868 issued September 6, 2005.

3. DeLuca et al U.S. Patent 6,277,837 issued August 21, 2001.

4. DeLuca et al U.S. Patent 5,354,744 issued October 11, 1994.

5. DeLuca et al U.S. Patent 4,717,721 issued January 5, 1988.

The Van Leeuwen et al article cited first above evidences that there is a clear correlation between the cell differentiation activity of vitamin D compounds and the relationship of such differentiation to the treatment of cancers. In particular, Applicant refers the Examiner to the section entitled "C. Differentiation" beginning at the bottom of page 1580 and continuing through the first column on 1581. Thus, cell differentiation is clearly evidence of effectiveness against numerous cancers including colon cancer, breast cancer and prostate cancer. The fact that 2MD causes differentiation of HL-60 leukemia cells evidences that 2MD causes differentiation of malignant cells in general and thus may be utilized to treat such cancers. In other words, differentiation of HL-60 leukemia cells by 2MD is one measure of its potential use in the treatment of cancers such as colon cancer, breast cancer or prostate cancer.

HL-60 cell differentiation activity has been accepted by the U.S. Patent Office for many years as providing sufficient support for claims to the treatment of various cancers. For example, the above cited U.S. Patent 6,939,868 is specifically directed toward a method of treating leukemia, colon cancer, breast cancer or prostate cancer (see claim 1) and the data which supported such claim consisted of the differentiation activity of HL-60 leukemia cells.

The above cited U.S. Patent 6,277,837 also has claims directed toward treating leukemia, colon cancer, breast cancer or prostate cancer (see claim 9) with the disclosed compounds. Again, the data supporting such a claim consisted of the differentiation activity of HL-60 leukemia cells.

U.S. Patent 5,354,744 is similar. Claim 14 of the '744 patent is directed toward a method of inhibiting proliferation of and for differentiating malignant cells of neoplastic diseases with the claimed compounds. Again, the differentiation of HL-60 cells in culture was used as the basis for supporting such claims (see example 5 at column 17, lines 1-35).

DeLuca et al U.S. 4,717,721 is also similar to the above in that claim 6 calls for a method of treating neoplastic diseases. The support for said claim consisted of the HL-60 cell differentiation activity of the tested compounds.

Applicant believes it has shown that the differentiation of HL-60 leukemia cells may be correlated to colon cancer, breast cancer and prostate cancer. It is clear from the Van Leeuwen et al article, for example, that cell differentiation of malignant cells such as HL-60 leukemia cells is a receptor mediated process and leukemia cells, colon cancer cells, breast cancer cells and prostate cancer cells all contain vitamin D receptors. Thus, the differentiation of HL-60 leukemia cells supports the use of 2MD in the treatment of colon cancer, breast cancer, and/or prostate cancer.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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